UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/534,711	03/24/2000	Philip O Livingston	53437-A-PCT-US/JPW/JL	2601

7590 04/06/2005

John P White
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 04/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/534,711	LIVINGSTON ET AL.	
	Examiner	Art Unit	
	Christopher H. Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8,11 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,11 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Re: Livingston P.O. *et al*
Priority Date: 25 September 1997

The amendment filed 12/17/2004 is acknowledged and entered into the record. Accordingly, claims 2-5,9-1012-13, and 15-16 are canceled without prejudice or disclaimer.

Claims 1,6-8,11, and 14 are pending and examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained - 35 USC § 103

The rejection of claims 1,6-8,11, and 14 under 35 USC § 103(a) as being obvious over Jennemann *et al* in view of Vangsted *et al* and Kensil *et al* is maintained for the reasons of record. Applicant argues that the amendment of the claims to reflect a molar ratio of the GM1-KLH conjugate is neither taught nor suggested in the cited references. Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record. The conjugate taught in the Jennemann *et al* and that instantly claimed are both conjugates comprising fucosyl GM1 and KLH. The amount or molar ratio claimed does not change the structure of the composition, because the amount of fucosyl GM1 and KLH added is viewed as a process of making the conjugate and therefore provide little patentable weight unless the process of making the conjugate confers a structural difference. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979). In the instant case, the applicant has not indicated that the process of adding GM1 and KLH in the ration of 400:1-1400:1 would inpart any structural difference or distinction for the conjugate taught by Jennemann *et al.* Therefore, the product taught in the prior art is the same as that instantly claimed.

Applicant additionally argues that the Jenneman *et al* teaches away from the claimed invention because the cited reference does not suggest using the instantly claimed QS-21 adjuvant. More specifically, applicant contends that Jennemann *et al* chose to use MPL as the immuno-adjuvant despite knowing or having available to them the QS-21 adjuvant. From this the applicant concludes that one of skill in the art would reasonable conclude that the reference teaches away from the claimed invention. Applicant's arguments have been carefully considered but are not deem persuasive to overcome the rejections of record. The arguments of counsel cannot take the place of evidence in

the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). In the instant case, applicant's conclusions are based on opinion and not on fact, nowhere in the Jennemann *et al* reference does it imply that the MPL adjuvant is better or worse than the QS-21 adjuvant. More over the claims are drawn in part to a composition and because one of skill in the art would reasonable conclude that the adjuvants taught by Jennmann *et al* would act in a similar manner, one of skill in the art would be motivated to use any adjuvant available to them at the time of the invention. Moreover given the fact that Jennmann *et al* taught that others have used QS-21 in conjunction with a similar conjugate (i.e. GM2-KLH conjugate) in phase I trials, would further motivate one of ordinary skill in the art to use QS-21 in place of MPL.

Applicant also argues that the reliance of Jennemann *et al* on Livingston *et al* (Vaccine 12(14):1275-1280) to establish that QS-21 would have the same effect in a composition comprising a different ganglioside conjugate (GM2-KLH) is misplaced. Specifically, applicant contends that the effects of QS-21 by Livingston *et al* can only be applied to GM2-KLH and Livingston *et al* provides no motivation or suggestion that QS-21 would have the same effect on another ganglioside. Applicant's arguments have been carefully considered but are not deemed persuasive because Jennemann *et al* clearly indicates that GM1-KLH conjugate is similar to that of GM2-KLH and therefore one of skill in the art would reasonable conclude from those statements that the effects of QS-21 on GM2-KLH would be the same or similar to those of GM1-KLH as instantly claimed.

Applicant also argues that the references of Vangsted *et al* and Kensil *et al* both do not provide any motivation to combine the components of the composition. Specifically, Vangsted *et al* is argues as teaching the use of fucosyl GM1 for treating SCLC and Kensil *et al* is argued as teaching the effects of *Quillaja* saponins on vaccines comprising KLH. Applicant's arguments have carefully considered but are not deemed persuasive to overcome the rejections of record because the cited references are to used in combination with Jennemann *et al* for the purposes of obviating the methods of enhancing an antibody response or a method treating SCLC comprising the administration of the claimed GM1-KLH conjugate. The motivation to combine the references stems from the fact that Jennemann *et al* teaches a composition comprising a GM1-KLH conjugate with a MPL adjuvant and further provides motivation to use a QS-21 adjuvant (see page 383) it is also taught by Jennemann *et al* that compositions comprising GM1-KLH conjugates canbe effective against SCLC (see page 383), Kensil *et al* provides additional motivation to use QS-21 in combination with KLH conjugates because it is taught that *Quallaja* saponins help to boost immune in subjects administered KLH conjugates, and Vangsted *et al* is provided to teach that SCLC express GM1 gangliosides and therefore is motivation to use the conjugate of Jennemann *et al.*

Finally, applicant contends that the instant invention demonstrates unexpected results, however, applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d

1586 (Bd. Pat. App. & Inter. 1991). The evidence relied upon should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Applicants have the burden of explaining the data in any declaration they proffer as evidence of non-obviousness." *Ex parte Ishizaka*, 24 USPQ2d 1621, 1624 (Bd. Pat. App. & Inter. 1992). In the instant case, the applicant has not submitted any evidence to indicate that the results are in fact unexpected over what would be expected in the prior art. For example, applicant claims that the IgG and IgM response were increased following the administration of the claimed compound. Jennemann *et al* also teach the same or similar increase in IgG and IgM response (see figure 2 page 581). Therefore, one of skill in the art would expect that the administration of the claimed compounds would also result in such an increase in immunoglobulins.

Therefore, the rejection of claims under 35 USC 103(a) as being obvious is maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 112, 2nd paragraph

Claims 1,6-8,11,14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, claims 1,6-8,11, and 14 recite the phrase "*wherein the fucosyl GM1 ganglioside derivative:Keyhole Limpet Hemocyanin molar ratio in the conjugate is from*

400:1 to 1400:1", the metes and bounds of the claims cannot be adequately determined because it is not clear whether 400 molecules of fucosyl GM1 ganglioside is conjugated 1 molecule of KLH or if the ratio refers to a process of reacting 400 molecules of GM1 to 1 molecule of KLH. Appropriate correction or clarification is required.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 1,6-8,11, and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION. The claims have been amended to recite a specific molar ratio of fucosyl GM1 ganglioside to KLH (i.e. 400:1-1400:1). The applicants point to page 23 for support, however upon closer review of the specification, the specification only provides support for 400:1 to 1400:1 of molecular weight and not of molar concentration as claimed. Applicant is required to specifically point to the specification for support or removed the amended material.

All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in a paper filed on 12/17/2004.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
March 30, 2005

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/29/05